

AMENDED IN SENATE JUNE 7, 2006  
AMENDED IN SENATE JUNE 23, 2005  
AMENDED IN ASSEMBLY MAY 26, 2005  
AMENDED IN ASSEMBLY APRIL 18, 2005  
AMENDED IN ASSEMBLY APRIL 7, 2005  
AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

## ASSEMBLY BILL

**No. 71**

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**Introduced by Assembly Members Chan and Frommer  
(Coauthors: Assembly Members Bass, Cohn, Evans, Gordon,  
Koretz, and Pavley)**

January 3, 2005

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An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

### LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: ~~Office of California Drug Safety Watch~~. *Drug Safety and Effectiveness Program.*

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would *request the University of California to establish the* ~~Office of California Drug Safety Watch within the department and~~

~~would require the office, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs that belong to classes of drugs for which there have been recently published reports of safety concerns, that have been frequently advertised directly to consumers, and for which there are recently published systematically reviewed evidence-based research that includes research on side effects and safety issues. The bill would require the office to a program to evaluate the safety and effectiveness of prescription drugs in California. This bill would request that the program include, among other things, a determination of the classes of drugs that are advertised to consumers, marketed to physicians, or both, in California, and an Internet Web site designed to disseminate information to health care professionals and consumers through an Internet Web site and to request assistance from the University of California and California State University on the relative safety and effectiveness of those drugs, as specified.~~

*This bill would require the department to impose a fee impose a fee, to be established by the University of California, on any manufacturer of drugs sold in the state to which the bill applies, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state. This bill would require the fee to be collected by the State Board of Equalization, and to be deposited into the Drug Safety and Effectiveness Program Fund, which would be created by the bill, and used, upon appropriation by the Legislature, for purposes of the bill.*

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Since 1997, when the United States Food and Drug
- 4 Administration (FDA) allowed drug manufacturers to advertise
- 5 directly to consumers, the amount spent on advertising has risen
- 6 dramatically.
- 7 (b) According to the United States General Accounting Office
- 8 (GAO) report, the pharmaceutical industry spent \$2.7 billion in
- 9 2001 on direct-to-consumer advertising. A December 6, 2004,

1 New York Times report states that such spending has reached  
2 \$3.8 billion.

3 (c) According to the same GAO report, while overall spending  
4 on drug promotion was less than spending on research and  
5 development (\$19.1 billion versus \$30.3 billion), spending on  
6 direct-to-consumer advertising is increasing at a faster rate than  
7 overall drug promotion spending or spending on research and  
8 development. Between 1997 and 2001, the increase in  
9 direct-to-consumer advertising was 145 percent compared to a 59  
10 percent increase for research and development.

11 (d) Although the FDA is responsible for postmarket  
12 surveillance of prescription drugs, numerous concerns have been  
13 raised about the adequacy of these efforts.

14 (e) An unpublished internal FDA study from 2002 revealed  
15 that 18 percent of FDA scientists reported being pressured to  
16 approve a new drug “despite reservations about the safety,  
17 efficacy or quality of the drug.”

18 (f) A 1999 FDA survey and a Kaiser Family Foundation  
19 survey both found that more than 50 million people respond to  
20 drug advertisements by asking their doctor whether the  
21 advertised medications might work for them. At the same time,  
22 both surveys showed that almost 60 percent of consumers found  
23 the side-effect warnings in these advertisements to be inadequate.

24 (g) Pressure to get new drugs to market, combined with the  
25 vast amount of drug marketing undertaken by manufacturers,  
26 make it difficult to address a threat once it is identified. Recent  
27 studies linking the use of popular, widely promoted prescription  
28 drugs to serious public health concerns point to the need for  
29 greater oversight to protect the public.

30 (h) Drugs that are frequently advertised to consumers present  
31 special safety concerns because direct-to-consumer advertising is  
32 likely to minimize potential side effects and safety concerns and  
33 because advertised drugs are likely to be highly utilized by  
34 Californians.

35 (i) Californians do not have a reliable central repository of  
36 information about prescription drug safety and effectiveness.

37 (j) California physicians and other prescribers could benefit  
38 from a reliable central repository of information about  
39 prescription drug safety and effectiveness.

(k) Various nationally respected sources of clinical information are available as sources for a central repository of information about prescription drug safety and effectiveness.

(l) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. ~~Office of California Drug Safety Watch~~*Drug Safety and Effectiveness Program*

~~111657.~~ (a) There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) ~~Establish a central repository of information about the safety and effectiveness of prescription drugs that are selected pursuant to subdivision (b). The repository shall not include information about any therapeutic class of drugs that is used primarily to treat mental illness.~~

(2) ~~Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved. The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."~~

(3) ~~Ensure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available. When there is no evidence supporting the differential impact of medication among various demographic groups, it shall be noted on the Internet Web site.~~

1 ~~(b) In selecting therapeutic drugs about which to develop~~  
2 ~~information, the office shall only include classes of drugs that~~  
3 ~~have all of the following characteristics:~~

4 ~~(1) Classes of drugs for which there have been recently~~  
5 ~~published reports of safety concerns.~~

6 ~~(2) Classes of drugs that have been frequently advertised~~  
7 ~~directly to consumers.~~

8 ~~(3) Classes of drugs for which there are recently published~~  
9 ~~systemically reviewed evidence-based research that includes~~  
10 ~~research on side effects and safety issues.~~

11 ~~(c) The office shall request the appropriate units of the~~  
12 ~~University of California and the California State University to~~  
13 ~~provide assistance in implementing this article.~~

14 ~~(d) The office shall coordinate its activities with other state~~  
15 ~~departments and agencies to avoid unnecessary duplication.~~

16 ~~(e) The office shall rely on systemically reviewed~~  
17 ~~evidence-based research.~~

18 ~~(f) The process that the office uses to identify relevant~~  
19 ~~research and standards of clinical evidence shall be transparent~~  
20 ~~and publicly available.~~

21 ~~111657.1. For purposes of this article, the following terms~~  
22 ~~have the following meanings:~~

23 ~~(a) "Evidence-based research" means research that is based on~~  
24 ~~clinical evidence, including therapeutic outcomes, and that uses a~~  
25 ~~hierarchy of evidence to evaluate the reliability of the research.~~  
26 ~~In well-conducted research, the hierarchy of evidence, from~~  
27 ~~highest to lowest, is the system review of randomized clinical~~  
28 ~~trials, individual randomized clinical trials, controlled trials,~~  
29 ~~cohort studies, and case control studies.~~

30 ~~(b) "Systematically reviewed" means review of~~  
31 ~~evidence-based research that uses rigorous, unbiased methods to~~  
32 ~~examine the similarities and differences of results across many~~  
33 ~~individual research studies. The goal of a systematic review is to~~  
34 ~~estimate the comparative effectiveness and safety of health care~~  
35 ~~treatments. A systematic approach to reviewing the evidence~~  
36 ~~increases the reliability of the results, and the transparency of the~~  
37 ~~procedures.~~

38 *111657. (a) The Legislature hereby requests the University*  
39 *of California to establish a program to evaluate the safety and*  
40 *effectiveness of prescription drugs in the state.*

1     ***(b) The Legislature requests that the program have the***  
2     ***following components:***

3     ***(1) A determination of the classes of drugs that are advertised***  
4     ***to consumers, marketed to physicians, or both, in the state.***

5     ***(2) An Internet Web site that will report information on the***  
6     ***safety and effectiveness of brand name and generic drugs in the***  
7     ***classes that are identified pursuant to paragraph (1), including,***  
8     ***when available, direct comparisons of relative safety and***  
9     ***effectiveness, and differential safety and effectiveness of specific***  
10    ***drugs according to age, gender, race, or ethnicity.***

11    ***(A) This Web site shall be designed to disseminate information***  
12    ***to health care professionals and consumers in the state, and may***  
13    ***include links to other relevant Web-based information, if that***  
14    ***information has been reviewed and approved by the University of***  
15    ***California. The Internet Web site shall include the following***  
16    ***statement: “Many factors enter into selecting the proper drug for***  
17    ***individual patients. Before changing any medication, a patient***  
18    ***should consult with his or her treating physician or other***  
19    ***prescriber.”***

20    ***(B) The Web site design shall ensure that the dissemination of***  
21    ***information is done in a culturally competent manner that***  
22    ***addresses the differential impact of medications within a class***  
23    ***based on gender, age, race and ethnicity, and other factors when***  
24    ***that information becomes available. Where studies are relied***  
25    ***upon, the demographics of the individuals studied shall be***  
26    ***included in the information disseminated.***

27    ***(c) In implementing this article, the Legislature requests that***  
28    ***the University of California rely on the best scientific information***  
29    ***that is available, as determined by the University, giving due***  
30    ***consideration to the diversity of the population of the State of***  
31    ***California.***

32    ***(d) The Legislature requests that the University of California***  
33    ***use a transparent and publicly available process to identify***  
34    ***relevant research and standards of clinical evidence.***

35    ***(e) The Legislature requests that the University of California***  
36    ***establish a clinical advisory panel that includes physicians and***  
37    ***pharmacists serving diverse communities to be available to***  
38    ***collectively prepare a timely, publicly available critique of the***  
39    ***information posted on the Web site, reflecting a range of opinion***  
40    ***about how the evidence should be interpreted.***

1 (f) *The program created by this article shall not include any*  
2 *therapeutic class of drugs that is used primarily to treat mental*  
3 *illness.*

4 (g) *In order to avoid conflicts of interest, the Legislature*  
5 *requests that the University of California develop and implement*  
6 *conflict of interest provisions to prohibit a person from*  
7 *participating in the implementation of this program when he or*  
8 *she knows or has reason to know that he or she has a material*  
9 *financial interest including, but not limited to, a person who has*  
10 *a consulting or other agreement with an organization that would*  
11 *be affected by this program.*

12 ~~111657.2.~~

13 ~~111657.1.~~ (a) There is hereby imposed, pursuant to this  
14 section, a fee on manufacturers of drugs sold in the state.

15 (b) (1) The specific fee to be assessed on a drug manufacturer  
16 shall be established by the ~~State Department of Health Services,~~  
17 *University of California*, to the maximum extent practicable, on  
18 the basis of a drug manufacturer's market share of the total  
19 amount of drugs sold in the state.

20 (2) A fee shall not be assessed on a drug manufacturer that can  
21 demonstrate, as determined by the ~~State Department of Health~~  
22 ~~Services,~~ *University of California*, that it does not manufacture  
23 drugs that have the characteristics described in *paragraph (1) of*  
24 *subdivision (b) of Section 111657.*

25 (c) The fee shall be assessed and collected annually by the  
26 State Board of Equalization in accordance with Part 22  
27 (commencing with Section 43001) of Division 2 of the Revenue  
28 and Taxation Code. The fees collected shall be deposited in the  
29 ~~Drug Safety Watch and Effectiveness Program~~ Fund, which is  
30 hereby established in the ~~State~~ Treasury. Moneys in the fund  
31 shall be expended, upon appropriation by the Legislature, for the  
32 purposes of this article, including the costs of the State Board of  
33 Equalization for collection and administration of fees. All interest  
34 earned on the moneys that have been deposited into the Drug  
35 ~~Safety Watch and Effectiveness Program~~ Fund shall be retained  
36 in the fund.

37 (d) The fees collected pursuant to this section and the earnings  
38 therefrom shall be used solely for the purposes of implementing  
39 this article. The ~~department~~ *University of California* shall not  
40 collect fees pursuant to this section in excess of the amount

- 1 reasonably anticipated by the ~~department~~ *University of California*
- 2 to fully implement this article. The ~~department~~ *University of*
- 3 *California* shall not spend more than it collects from the fees, and
- 4 the earnings thereon, in implementing this article.